

IRISH MEDICINES BOARD ACT 1995

EUROPEAN COMMUNITIES (ANIMAL REMEDIES) (No. 2) REGULATIONS 2007

(S.I. No. 786 of 2007)

VPA: **10095/003/001**
Case No: 7001144

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

Rice Steele & Company Limited

Cookstown Industrial Estate, Tallaght, Dublin 24, Ireland

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

Flok Veterinary Healing Ointment

The particulars of which are set out in Part 1 and Part 2 of the said Schedule. The authorisation is also subject to any special conditions as may be specified in the said Schedule.

The authorisation, unless previously revoked, shall continue in force from **30/09/2006**.

Signed on behalf of the Irish Medicines Board

A person authorised in that behalf by the said Board.

(NOTE: From this date of effect, this authorisation replaces any previous authorisation in respect of this product which is now null and void.)

Part II

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Flok Veterinary Healing Ointment

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances

Chlorhexidine Hydrochloride 1.00% w/w

Cypermethrin (50:50) 0.05% w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Bright yellow greasy ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

As a healing aid for cuts, wounds, sores, cracked and hard teats, surface infections and damaged broken skin in cattle.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

In milking cows, wash the treated teat and udder before milking and dry with a disposable paper towel.

Special precautions to be taken by the person administering the product to animals

Disposable gloves should be used when handling this product. Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

This product may be used to treat pregnant and lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For topical administration.

Clean and dry the affected area before application.

General: Apply Flok Ointment twice daily.

Milking cows: Apply Flok Ointment after milking. Wash teats and udder before milking and dry with a disposable paper towel.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: zero days

Milk: zero days

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

ATCvet Code: QD08AC02: Dermatologicals - antiseptics and disinfectants

5.1 Pharmacodynamic properties

Flok Veterinary Healing Ointment acts locally on the skin as a healing aid.

Chlorhexidine is a cationic bis-biguanide antiseptic and disinfectant which exerts its effects on the cell membrane. It exhibits antimicrobial activity against a wide range of Gram-positive and Gram-negative micro-organisms and is also active against some fungi, yeasts and viruses. Chlorhexidine is rapidly biocidal at the concentrations used in Flok Veterinary Healing Ointment.

Cypermethrin is a synthetic pyrethroid insecticide which acts as a contact poison for insects. It has a stimulant and convulsive effect and rapidly causes paralysis leading to insect death. Cypermethrin acts as an insect repellent at the concentrations used in Flok Veterinary Healing Ointment, probably due to its stimulant action.

5.2 Pharmacokinetic properties

No information available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Yellow Soft Paraffin
Cetostearyl Alcohol
Liquid Paraffin
Isopropyl Myristate
Turmeric

6.2 Incompatibilities

Does not work well with anionic detergents.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Store below 25°C. Protect from light.

6.5 Nature and composition of immediate packaging

Polypropylene container with a polyethylene lid containing 200 g of a bright yellow greasy ointment or a polyethylene container with a polypropylene lid containing 2 kg of bright yellow greasy ointment.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Ricesteele Manufacturing Ltd.,
Cookstown Industrial Estate,
Tallaght,
Dublin 24,
Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10095/3/1

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2006